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ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) Title: PROCESS FOR THE PREPARATION OF ROBUST FORMULATIONS OF VALACYCLOVIR HYDROCHLORIDE  
TABLETS

(57) Abstract: The invention relates to robust formulations of valacyclovir hydrochloride tablets. A robust tablet includes a hydrated form of valacyclovir hydrochloride having a water of hydration content of more than approximately 3% w/w and a particle size of less than approximately 355  $\mu\text{m}$ .

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## INTERNATIONAL SEARCH REPORT

Internationale Application No

PCT/IB 03/02456

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61K9/20 A61K31/522

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 25989 A (GLAXO) 24 July 1997 (1997-07-24) claims examples ---	1-43
X	WO 96 22291 A (WELLCOME FOUNDATION) 25 July 1996 (1996-07-25) cited in the application claims examples 5,6 ---	1-43
X	WO 96 22082 A (WELLCOME FOUNDATION) 25 July 1996 (1996-07-25) cited in the application claims examples --- -/-	1-43

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

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- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 32097 A (PHARMA PASS) 17 October 1996 (1996-10-17) claims 1-5,12,19-26 examples 1,2,11 -----	1-43
A,P	WO 03 022209 A (TEVA) 20 March 2003 (2003-03-20) claims 6,56,64 -----	1-43

# INTERNATIONAL SEARCH REPORT

International application No.  
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## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claims 22-27 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International Application No

PCT/IB 03/02456

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9725989	A	24-07-1997	AT 254463 T	15-12-2003
			AU 722304 B2	27-07-2000
			AU 1443497 A	11-08-1997
			CA 2243237 A1	24-07-1997
			DE 69726255 D1	24-12-2003
			WO 9725989 A1	24-07-1997
			EP 0874631 A1	04-11-1998
			JP 2000503310 T	21-03-2000
			ZA 9700400 A	13-11-1997
WO 9622291	A	25-07-1996	AP 662 A	19-08-1998
			AU 702794 B2	04-03-1999
			AU 4453996 A	07-08-1996
			BG 63393 B1	31-12-2001
			BG 101833 A	30-04-1998
			BR 9606768 A	30-12-1997
			CA 2210799 A1	25-07-1996
			CN 1179159 A ,B	15-04-1998
			CZ 9702294 A3	17-12-1997
			EA 364 B1	24-06-1999
			EE 9700175 A	16-02-1998
			EP 0804436 A1	05-11-1997
			FI 973063 A	18-09-1997
			WO 9622291 A1	25-07-1996
			HR 960024 A1	31-10-1997
			HU 9801836 A2	28-05-1999
			IL 116831 A	30-10-1998
			IN 182468 A1	17-04-1999
			JP 3176633 B2	18-06-2001
			JP 11503718 T	30-03-1999
			NO 973326 A	16-09-1997
			NZ 298851 A	28-01-1999
			OA 10499 A	10-04-2002
			PL 321326 A1	08-12-1997
			RO 118693 B1	30-09-2003
			SK 96597 A3	04-02-1998
			TR 9700656 T1	21-03-1998
			US 6107302 A	22-08-2000
			ZA 9600449 A	07-08-1996
WO 9622082	A	25-07-1996	AP 666 A	24-08-1998
			AT 190483 T	15-04-2000
			AU 710823 B2	30-09-1999
			AU 4453496 A	07-08-1996
			BG 63187 B1	29-06-2001
			BG 101831 A	30-04-1998
			BR 9606769 A	30-12-1997
			CA 2210891 A1	25-07-1996
			CN 1179100 A ,B	15-04-1998
			CY 2182 A	23-08-2002
			CZ 9702292 A3	18-02-1998
			DE 69607146 D1	20-04-2000
			DE 69607146 T2	21-09-2000
			DK 806943 T3	24-07-2000
			EA 276 B1	25-02-1999
			EE 3336 B1	15-02-2001
			EP 0806943 A1	19-11-1997
			ES 2145425 T3	01-07-2000

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International Application No

PCT/IB 03/02456

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9622082	A	FI 973062 A	18-09-1997
		WO 9622082 A1	25-07-1996
		GR 3033677 T3	31-10-2000
		HK 1002851 A1	08-09-2000
		HU 9801872 A2	28-10-1999
		IL 116830 A	29-02-2000
		IN 181318 A1	09-05-1998
		JP 3350055 B2	25-11-2002
		JP 10512564 T	02-12-1998
		NO 973327 A	16-09-1997
		NZ 298846 A	26-06-1998
		OA 10500 A	10-04-2002
		PL 321361 A1	08-12-1997
		PT 806943 T	31-08-2000
		RO 118175 B1	28-03-2003
		SI 806943 T1	31-08-2000
		SK 96497 A3	14-01-1998
		TR 9700657 T1	21-02-1998
		US 5879706 A	09-03-1999
		ZA 9600448 A	07-08-1996
WO 9632097	A 17-10-1996	AT 214596 T	15-04-2002
		AU 5652796 A	30-10-1996
		CA 2218054 A1	17-10-1996
		DE 69619979 D1	25-04-2002
		DE 69619979 T2	21-11-2002
		EP 0830129 A1	25-03-1998
		WO 9632097 A1	17-10-1996
		US 6348469 B1	19-02-2002
		US 6117453 A	12-09-2000
WO 03022209	A 20-03-2003	WO 03022209 A2	20-03-2003
		US 2003114470 A1	19-06-2003
		WO 03041647 A2	22-05-2003
		US 2003153757 A1	14-08-2003